

EXHIBIT C

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION,

MDL No. 2419

Master Dkt: 1:13-md-02419-RWZ

THIS DOCUMENT RELATES TO:

All Actions Naming St. Thomas Outpatient
Neurosurgical Center

Videotaped Deposition of:

LAURA THOMA, PHAR. M.D.

Taken on behalf of the Plaintiffs
MARCH 8, 2016

A P P E A R A N C E S

For the Plaintiffs:

MR. BEN GASTEL
Attorney at Law
Law Offices of Branstetter, Stranch &
Jennings, PLLC
223 Rosa L. Parks Avenue, Suite 200
Nashville, TN 37203
(615)254-8801
Beng@bsjfirm.com

MR. FREDRIC L. ELLIS
Attorney at Law
Law Offices of Ellis & Rapacki, LLP
85 Merrimac Street, Suite 500
Boston, MA 02114
(617)523-4800
Rellis@ellisrapacki.com

For the Defendants:

MR. MATT CLINE
Attorney at Law
Law Offices of Gideon, Cooper and Essary
316 Deaderick Street, #1100
Nashville, TN 37238
(615)254-0400
Mcline@gideoncooper.com

MR. ADAM T. SCHRAMEK
Attorney at Law
Law Offices of Norton Rose Fulbright, US, LLP
98 San Jacinto Boulevard, Suite 1100
Austin, TX 78701-4255
(512)474-5201
Adam.schramek@nortonrosefulbright.com

MR. PARKS T. CHASTAIN
Attorney at Law
Law Offices of Brewer, Krause, Brooks &
Chastain, PLLC
611 Commerce Street, Suite 2600
Nashville, TN 37203
(615)630-7717

Also Present: Randy Lawson, Videographer

1 A. Okay.

2 Q. Tell me if I'm reading this right, second
3 sentence of the full first paragraph. "USP 797 only
4 recommends that test samples be finished
5 preparations." Have I read that right?

6 A. You sure did.

7 Q. Did you write this and submit it --

8 A. I sure did.

9 Q. -- two months ago, three months ago?

10 A. Yeah.

11 Q. Now, you also criticize the sterile -- the
12 autoclaving process in this case because it only was
13 autoclaved for 15 minutes; is that correct?

14 A. Yes.

15 Q. And you said that USP 797 requires a minimum
16 of 20 minutes at 121 degrees. Is that what you -- is
17 that your opinion?

18 A. Yes. Well, that's a commonly --
19 sterilization time, 20 minutes. I mean, 20 is going
20 to give you ten to the minus six. If you have the
21 normal D-value for your biological indicators.

22 Q. Can you answer my question? Is it your
23 opinion that USP 797 requires autoclaving for
24 20 minutes at 121 degrees centigrade? Was that your
25 opinion?

1 A. I think there was an example in there. Let
2 me see.

3 Q. I'm just asking as we sit here today, is that
4 your opinion, Dr. Thoma?

5 A. I believe that it gives a recommendation of
6 20, but I understand also they could have something
7 really big in there or something really small.

8 Q. So can you answer my question?

9 A. Do I believe --

10 Q. That chapter -- that USP --

11 A. Clearly states that minimum of 20 minutes is
12 required.

13 Q. That's the question.

14 A. Well, I thought it did, but let me find it.
15 Did I miss the sterilization section? Hang on.
16 Sorry, guys.

17 "To achieve sterility, all materials are
18 exposed to steam at 121 under one -- under a pressure
19 of about one atmosphere of 15 PSI for the duration
20 verified by testing to achieve sterility of the
21 items, which is usually 20 to 60 minutes for PSC."

22 Q. Okay. So wait a second here. I don't see
23 that where it says 20 minutes is required at
24 121 degrees. Is that your reading of that?

25 A. It said usually.

1 Q. It says usually. Does it say --

2 A. So it's going to be 20 minimum, so 15, 20.

3 So --

4 Q. Fifteen could be okay sometimes?

5 A. Not for what they were trying to do.

6 Q. Fifteen minutes can be okay under certain
7 circumstances, correct?

8 A. Could be. Does that make you happy now?

9 Q. Well, let me show you Exhibit 11 --

10 MR. SCHRAMEK: Yes, he loves defending
11 NECC's honor, if you haven't noticed.

12 MR. ELLIS: Okay. Let's cut the
13 comments. Okay? I'm just doing my job here, Adam.
14 Okay? Leave me alone. You're the one trying to
15 blame everybody else apart from yourselves from this.

16 MR. CLINE: After you guys have sued them
17 all.

18 MR. SCHRAMEK: And taking their money.

19 MR. ELLIS: And why do you think we
20 settled with them? Because you can't prove a damn
21 case against them. You guys know that, too.

22 MR. SCHRAMEK: Make sure. They may have
23 a fraudulent inducement claim.

24 THE WITNESS: Okay. Where are we at?

25 BY MR. ELLIS:

C E R T I F I C A T E

STATE OF TENNESSEE
COUNTY OF SHELBY

I, LISA J. MAYO, RMR, CRR, Licensed Court Reporter, with offices in Memphis, Tennessee, hereby certify that I reported the foregoing deposition of LAURA THOMA by machine shorthand to the best of my skills and abilities, and thereafter the same was reduced to typewritten form by me.

I further certify that I am not related to any of the parties named herein, nor their counsel, and have no interest, financial or otherwise, in the outcome of the proceedings.

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